



# The Technical Compliance Manager

Avoiding Non-Compliance in the technical area

3 - 5 June 2014, Berlin, Germany

## SPEAKERS:

**Dr Gerhard Hauser**  
*European Hygienic Engineering and Design Group (EHEDG)*

**Dr Jean Denis Mallet**  
*ECA & Former Head of the French Pharmaceutical Inspection Dpt. AFSSAPS*

**Gert Moelgaard**  
*NNE Pharmaplan*

**Markus Rohde**  
*CSL Behring*

**Wolfgang Rudloff**  
*gmp-experts*

**Dr Ingrid Walther**  
*Former Head of the Business Unit iv Drugs, Fresenius*

## LEARNING OBJECTIVES:

- Quality Systems & Documentation
- Regulatory Affairs for Engineers
- Fundamentals of Pharmaceutical Technology
- GMP-compliant Equipment Design
- Requirements on Materials and Surfaces
- GMP requirements for Cleanrooms and HVAC Systems
- Re-Construction and Renovation of Facilities
- GMP-compliant Water Systems
- Qualification, Re-Qualification and Commissioning
- Technical Change Control
- Maintenance & Calibration
- Auditing Technical Suppliers
- Impact of the new GMP Thinking on engineering



# The Technical Compliance Manager

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## Objectives

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This course explains how the requirements laid down in the GMP and FDA regulations can be put into **technological and engineering practice**. The whole lifecycle from the design, the qualification and the maintenance of equipment is covered. An outlook to the upcoming changes to the engineering regulations is also given.

## Background

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Technical compliance is a wide field, especially when taking into account the ICH framework which covers the whole lifecycle of pharmaceutical manufacturing. It does not only mean to comply with regulatory guidelines but also with submissions and the technological state of the art, meaning ISO and other standards as well as accepted good practices in the pharmaceutical industry.

In this GMP course we want to focus on the main topics with regard to technical compliance:

### Background knowledge

There are a number of quality assurance systems which are crucial for the technical units. Furthermore, beside the fundamentals of pharmaceutical technology for the key operations like tableting and sterile filling, understanding the role of engineering in regulatory submissions facilitates daily work.

### GMP Facility & Re-Construction

Designing an appropriate layout belongs to this part as well as understanding what the GMP requirements for the cleanrooms and for the HVAC systems are, depending on the type of manufacture. Re-Construction during on-going manufacture is supreme discipline in this field.

### GMP-compliant design of equipment

A GMP-compliant design of equipment is the basis for fulfilling the technical requirements. In this respect, engineering assumes a prominent role in ensuring the safety of medicinal products. In this context, the need for material certificates is often subject to discussion.

### Validation / Qualification

Not only GMP regulations but also inspectors consider qualified equipment and validated processes as the prerequisites for producing pharmaceutical quality. The identification of the equipment that has to be qualified by means of a risk analysis is a crucial point. This field has now re-gained considerable attention as the regulations are changing: After FDA's new guide on validation (and process verification), Annex 15 of the EU GMP Guide is now subject to revision.

## Routine Operation and technical QA aspects:

Preventive maintenance in pharmaceutical production as well as the documentation of changes are essential elements of the Pharmaceutical Quality System. Systems for calibration & handling technical failures, which are checked frequently during inspections, are of equal importance for maintaining the qualified state. Finally, auditing the own technical suppliers is a recurring activity from the beginning of a project until the outsourcing of engineering activities later on.

## Target Audience

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This course is directed at staff in pharmaceutical manufacture, at technicians, engineers, planners and plant constructors who are involved in tasks related to engineering work in a cGMP environment.

## Programme

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### Impact of Regulatory Requirements on engineering

- Important guidelines with technical content
- GMP compliant documentation in the technical environment
  - QA systems with technical relevance
  - Change Control
  - Deviation / CAPA
  - Training
- Classification of technical deviations
- Correlation of technical malfunctions with the CAPA system & batch release
- Documentation in logbook and higher-level systems

*Dr Ingrid Walter*

### Qualification, Re-Qualification & Commissioning

- Using risk analysis from kick-off to routine operation
- Handling impact and no-impact systems
- From the URS to PQ: step by step
- System Verification
- Re-Qualification: how to...? And how often?
- Examples

*Markus Rohde*

### Regulatory Affairs for Engineers

- Types of Submissions in EU and US
- Structure and Content of submissions
- Technical Details which should or should not be written in filings to authorities

*Dr Ingrid Walter*

### Materials and Surfaces

- Which materials can be used and for what purpose?
- Stainless steel, plastics, polymers,...
- How smooth have surfaces to be? Roughness and structures of cleanable surfaces
- What are the requirements on welding?
- Effects of corrosion, failures, and damage

*Dr Gerhard Hauser*

### **GMP-compliant equipment design**

- Open and closed systems
- Overview on important construction details for sterile and non-sterile applications
- Design of gaskets and problems with gaskets
- Allowed lubricants
- Valves
- Pumps
- Examples of GMP-compliant equipment

*Dr Gerhard Hauser*

### **Requirements for cleanrooms and HVAC systems for different dosage forms**

- Cleanroom standards, cGMP Regulations, and their interaction
- Finding the correct requirements depending on the manufacturing operation
- Protection concepts, types of air flows
- Defining an appropriate layout and air lock concept
- Requirements on floor, ceiling and walls
- Some HVAC system concepts-comparison fresh air / recirculating air
- Particle testing depending on the cleanroom zone
- Qualification of Cleanrooms
- Re-Qualification of rooms and air-handling systems

*Dr Jean-Denis Mallet*

### **Upgrading, re-construction and renovation of facilities**

- How to handle documentation gaps
- How to protect the ongoing manufacturing operations
  - Protection of products
  - Protection of equipment, rooms and HVAC
  - Personal flow and handling of external personal, Access control
  - Documentation of protective measures
- What to consider in re-construction projects?
- Examples from recent projects

*Markus Rohde*

### **Technical Change Control**

- Definitions of change management
- Regulatory aspects
- How to maintain a change control system
- Link between maintenance, change control and deviations
- Classification of technical changes
- Examples

*Dr Ingrid Walter*

### **Qualification and Management of technical suppliers**

- Selection and auditing of suppliers with a risk based approach
- How much GMP must a supplier have?
- Review of suppliers and their performance
- How to audit a technical supplier?
- Examples of managing suppliers for equipment, equipment parts, technical services, ..

*Markus Rohde*

### **Pharmaceutical Water Systems: Production & Storage and Distribution**

- Influence of raw water
- Schematic water generation: Aqua Purificata, WFI
- Components: working principles and hazards (Softening, EDI, RO,...)
- Loop concepts
- What to measure and control (physical and chemical)
- Modern sanitisation concepts, avoidance of biofilms
- How to handle OOS in a water system

*Wolfgang Rudloff*

### **Fundamentals of pharmaceutical technology**

- Manufacture of oral solid dosage forms
  - Fundamentals of Granulation
  - Compaction/Tableting
  - Critical Process Parameters (CPQs) (how machine parameters affect the efficacy of a tablet)
  - Equipment requirements
- Sterile and aseptic operations
  - Compounding & filling
  - Machine concepts
  - Filtering
  - Critical Process Parameters (CPQs)
  - 100% controls
  - Media Fills

*Dr Jean-Denis Mallet*

### **Maintenance & Calibration**

- Maintenance/calibration in the life-cycle model of pharmaceutical equipment
- How to set up and maintain a maintenance/calibration system
- How to define frequencies, activities, tolerances, acceptance criteria, etc.
- Permanent conflict: maintenance/calibration or production
- Documentation & labeling
- Data integrity

*Wolfgang Rudloff*

### **Impact of the new GMP Thinking on engineering**

- Revision of Annex 15
- State of validation / qualification in the US
- Impact of ASTM E 2500 on European projects
- Changes coming from ICH Q 8-10
- How to comply with EU and US requirements in technical projects
- Practical examples

*Gert Moelgaard*

## Speakers

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### **Dr Gerhard Hauser,**

*Formerly Technical University of Munich;  
Member of the EHEDG*

Dr Hauser was senior engineer at the chair of mechanical and plant engineering of Munich Technical University. He was also a member of the German mirror body for the European machinery directive (standardisation of hygiene and cleaning requirements on machines used in the food industry), member of the European Hygienic Engineering and Design Group (EHEDG), Chairman of the subgroup 'Design Principles'. Now he is still giving lectures on hygienic design at the University of Karlsruhe. He has recently published two books on Hygienic Design.



### **Dr Jean-Denis Mallet,**

*ECA, former head of the French Inspection  
Department AFSSAPS, NNE Pharmaplan*

Jean-Denis Mallet is a pharmacist. He was previously the Head of the Pharmaceutical and Cosmetics Inspection Department at the French Health Products Regulatory Agency (Afssaps= ANSM). He also used to work in or with the pharmaceutical industry during many years at various positions including Quality Assurance, Production Management, Engineering and GMP Consulting. He has also been auditor of the International Red Cross. Now he is member of the ECA advisory board and works for NNE Pharmaplan.



### **Gert Moelgaard,**

*NNE Pharmaplan*

Gert Moelgaard is Vice President for Innovation & Business Development in NNE Pharmaplan. He has been working in the pharmaceutical industry since 1982 and has experience from a number of major engineering, automation and validation projects within pharmaceutical manufacturing. He has made international contributions in international conferences on automation, process validation, PAT and manufacturing excellence and has contributed to several books and technical guidelines.



### **Markus Rohde,**

*CSL Behring GmbH*

Markus Rohde works for CSL Behring in Marburg in the position of the Deputy Head of the department Quality Management Engineering and as group leader for the qualification of equipment and utilities as well as for validation of automated systems.



### **Wolfgang Rudloff,**

*GMP-Experts*

Mechanical Engineer, legal expert in cleanroom technology and GMP-management, expert in Industrial Engineering, worked in technical and process lead positions within Warner Lambert (now Pfizer) in Freiburg. His qualification comprises lead auditor, head of construction management, process engineering, GMP consultancy. After the position as managing director of LSMW / Switzerland he became in 2001 managing director for PCS. Today, he is a freelance consultant specialised in technical GMP management, auditing and training.



### **Dr Ingrid Walther**

*Pharma Consulting Walther*

Dr Walther joined Fresenius AG in 1986. She was employed in various positions and has long years of experience in the fields of research and development, quality assurance/quality control and the management of strategic projects. In 1997 she assumed a position as head of the Business Unit Validation and GMP Compliance at Pharmaplan GmbH. In a subsequent position at Pharmaplan, she became responsible for consulting projects and became COO. In 2007, she re-joined Fresenius, heading the business unit iv Drugs & Oncology. Since July 2009 she runs her own business as consultant.

## Social Event

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On Tuesday, 3 June 2014 you are cordially invited to a social event. This is an excellent opportunity to share your experiences with colleagues from other companies in a relaxed atmosphere.



## Organisation and Contact

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CONCEPT HEIDELBERG  
P.O. Box 10 17 64  
D-69007 Heidelberg, Germany  
Phone +49 (0) 62 21/84 44-0,  
Fax +49 (0) 62 21/84 44 34  
E-mail: [info@concept-heidelberg.de](mailto:info@concept-heidelberg.de)  
[www.concept-heidelberg.de](http://www.concept-heidelberg.de)

### For questions regarding content:

Dr Robert Eicher (Operations Director) at  
+49-62 21 / 84 44 12, or per e-mail at  
[eicher@concept-heidelberg.de](mailto:eicher@concept-heidelberg.de).

### For questions regarding reservation, hotel, organisation etc.:

Ms Jessica Stürmer (Organisation Manager) at  
+49-62 21 / 84 44 43,  
or per e-mail at [stuermer@concept-heidelberg.de](mailto:stuermer@concept-heidelberg.de).

## Conference Folder

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You cannot take part in this event? Just order the documentation at the price of € 380.- + VAT + postage and packing. You can use the registration form for this purpose. Please note: In order to ensure that the documentation is complete, The conference folder will not be available until 2 weeks after the event.

## GMP Certification Programme

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This seminar is recognised within the GMP Certification Programme. By attending selected seminars, the participant can acquire an additional certificate. We offer the following modules:

ECA Certified Validation Manager  
ECA Certified QA Manager  
ECA Certified API Production Manager  
ECA Certified Quality Control Manager  
ECA Certified Technical Operations Manager  
ECA Certified Computer Validation Manager  
ECA Certified Regulatory Affairs Manager  
ECA Certified Microbiological Laboratory Manager  
ECA Certified Sterile Production Manager  
ECA Certified Biotech Manager  
ECA Certified Pharmaceutical Development Manager

On the internet at [www.gmp-compliance.org](http://www.gmp-compliance.org) you will find a text explaining which seminars are recognised for which certificates. Or you send an e-mail to [info@gmp-compliance.org](mailto:info@gmp-compliance.org) or a fax to +49-6221- 84 44 64 with the request for information about the GMP Certification Programme. We will then send you our brochure on the topic.

## What are The ECA Foundation and the ECA Academy?

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The European Compliance Academy Foundation (ECA Foundation) is an independent professional organisation chaired by a Scientific Advisory Board with members from the pharmaceutical industry and regulatory authorities. The ECA Foundation's goal is to support to the Pharmaceutical Industry and Regulators to promote the move towards a harmonised set of GMP and regulatory guidelines by providing information and interpretation of new or updated guidances. The ECA Academy offers professional basic and advanced education (training) programmes. All services offered by the ECA Academy and with regard to ECA Academy Memberships are solely managed by Concept Heidelberg (a leading European training and information services provider). The ECA Foundation is conceptual sponsor of the ECA Academy.

## How Do You Become a Member of ECA?

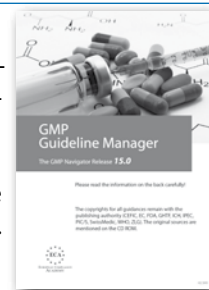
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By participating in one of the ECA Academy Conferences or Courses you will automatically become a ECA Academy Individual Member for two years - free of charge. More information about ECA Academy can be obtained on the Website <http://www.gmp-compliance.org>

## What Are the Benefits of ECA?

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During the membership, you enjoy a EUR 200,- discount on the regular participation fee of any European Conference or Course presented by the ECA Academy. In addition you will receive the GMP Guideline Manager Software with a large number of guidelines, e.g. EC Directives, FDA Guidelines, ICH Guidelines.



## Lufthansa is Mobility Partner for all ECA Events

As an ECA course or conference attendee, you will receive up to 20% discounted travel fares (according to availability). And as Lufthansa German Airlines offers a comprehensive global route network linking major cities around the world you will most likely be able to benefit from these special prices and conditions.

And this is how it works: Once you registered for a course or conference you will receive a link together with your registration confirmation. Opening that link will take you to the Mobility Partner Program website where you can enter a code in the "Access to Event Booking" area you will also receive. This will take you into an online booking platform\* that will automatically calculate the discount offered or provide you with an even better offer if another promotional fare is available.

We look forward to welcoming at one of our next events – and we already wish you a pleasant flight!

\*Please note: You may have to enable pop-ups on the Mobility Partner Program website – other-wise the booking platform window will not open.

## Easy Registration



Reservation Form:  
**CONCEPT HEIDELBERG**  
P.O. Box 10 17 64  
69007 Heidelberg  
Germany



Reservation Form:  
+ 49 6221 84 44 34



e-mail:  
info@concept-heidelberg.de



Internet:  
www.gmp-compliance.org

Reservation Form (Please complete in full)

### The Technical Compliance Manager

3-5 June 2014, Berlin, Germany

Mr.  Ms.

Title, first name, surname

Company

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#### General terms and conditions

- If you cannot attend the conference you have two options:
1. We are happy to welcome a substitute colleague at any time.
  2. If you have to cancel entirely we must charge the following processing fees: Cancellation
    - until 2 weeks prior to the conference 10 %
    - until 1 week prior to the conference 50 %
    - within 1 week prior to the conference 100 %.

CONCEPT HEIDELBERG reserves the right to change the materials, instructors, or speakers without notice or to cancel an event. If the event must be cancelled, registrants will be notified as soon as possible and will receive a full refund of fees paid. CONCEPT HEIDELBERG will not be responsible for discount airfare penalties or other costs incurred due to a cancellation.

**Terms of payment:** Payable without deductions within 10 days after receipt of invoice.  
**Important:** This is a binding registration and above fees are due in case of cancellation or non-appearance. If you cannot take part, you have to inform us in writing. The cancellation

fee will then be calculated according to the point of time at which we receive your message. In case you do not appear at the event without having informed us, you will have to pay the full registration fee, even if you have not made the payment yet. Only after we have received your payment, you are entitled to participate in the conference (receipt of payment will not be confirmed). (As of January 2012)

#### Date

Tuesday, 3 June 2014, 9.00 to approx. 18.15 h  
(Registration and coffee 8.30 – 9.00 h)

Wednesday, 4 June 2014, 8.30 to approx. 17.15 h

Thursday, 5 June 2014, 8.30 to approx. 15.45 h

#### Venue

NH Berlin Mitte

Leipziger Strasse 106-111

10117 Berlin, Germany

Phone +49-30-20376-0

Fax +49-30-20376-600

#### Fees

ECA Members € 1,790.-

per delegate plus VAT

APIC Members € 1,890.-

per delegate plus VAT

Non-ECA Members € 1,990.-

per delegate plus VAT

EU GMP Inspectorates € 995.-

per delegate plus VAT

The conference fee is payable in advance after receipt of invoice and includes conference documentation, dinner on the first day, lunch on all three days, and all refreshments. VAT is reclaimable.

#### Accommodation

CONCEPT HEIDELBERG has reserved a limited number of rooms in the conference hotel. You will receive a room reservation form when you have registered for the event. Please use this form for your room reservation to receive the specially negotiated rate for the duration of your stay. Reservation should be made directly with the hotel. Early reservation is recommended.

#### Registration

Via the attached reservation form, by e-mail or by fax message. Or you register online at [www.gmp-compliance.org](http://www.gmp-compliance.org).

#### Conference language

The official conference language will be English.